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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,859	10/01/2008	Herbert Moessler	2006_1221A	9760

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EXAMINER	
LIEB, JEANETTE	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
08/03/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/587,859	MOESSLER ET AL.
	Examiner	Art Unit
	JEANETTE LIEB	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), an international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an international application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination of whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 C.F.R. 1.475 (e).

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted

Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-8, drawn to a dietary supplement composition comprising a protein having either the sequence NMVPFPR or ASAFQGIGSTHWVYDGVGNS.

II. Claims 9-15, drawn to a method of treating cognitive diseases and conditions with NMVPFPR or ASAFQGIGSTHWVYDGVGNS.

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 because, pursuant to 37 C.F.R. § 1.475(a), the composition defined in the claims lack the special technical feature that defines a contribution over the prior art. The technical feature in the instant claims is a peptide parathyroid hormone fragment wherein the structure conforms to: NMVPFPR or ASAFQGIGSTHWVYDGVGNS.

This structure is not a special technical feature that is over the prior art.

The MPEP states if "an independent claim does not avoid the prior art, then the question whether there is still and inventive link between all the "claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection for lack of unity, *a posteriori* (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination subcombination situation."

In the instant case, the sequences of claim 1 are known in the art. SEQ ID NO: 1 is taught by Rudolph et. al. as corresponding to residues 256-262 of Beta-Tubulin (see p. 2236; *Three Drosophila Beta-Tubulin Sequences: a Developmentally Regulated Isoform (13), the Testis-Specific Isoform ((2), and an Assembly-Defective Mutation of the Testis-Specific Isoform (B2t8) Reveal Both an Ancient Divergence in Metazoan Isotypes and Structural Constraints for*

Beta-Tubulin Function, MOLECULAR AND CELLULAR BIOLOGY, June 1987, p. 2231-2242). Additionally, Sautter et. al. teach SEQ ID NO: 2 as corresponding to residues 426-446 of the cyclic nucleotide gated beta subunit (p.4697, *An isoform of the rod photoreceptor cyclic nucleotide-gated channel b subunit expressed in olfactory neurons*, PROC. NATL. ACAD. SCI. USA Vol. 95, pp. 4696–4701, April 1998).

Groups I and II are not linked by "special technical features" because claims 1-8 are drawn to peptides comprising SEQ ID's 1 and 2, and claims 9-15 are drawn to a method of treating neurological diseases using peptides comprising SEQ ID NO's 1 and 2. The only common element in either group are the compounds NMVPFPR and ASAFQGIGSTHWVYDGVGNS, which is does not allow the claims to be a unified invention over the prior art based on the teachings of Rudolph et al. and Sautter et. al.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to more than one of the following patentably distinct species:

1. SEQ ID NOs: 1 and 2, with regards to the composition.

2. 21 distinct species of the method in claims 9, 11, 12, 13, 14, and 15: 1) age-associated memory impairment, 2) age- associated cognitive decline, 3) benign senescent forgetfulness, 4) protect neurons against metabolic deficits and stress associated with aging processes, 5) the consequences of age-related neuronal lesions due to hypoxia or ischemia, 6) the consequences of age-related neuronal lesions due to intracellular calcium overload, 7) the consequences of age-related neuronal lesions induced by L-glutamate and excitotoxic events, 8) the consequences of age-related neuronal lesions due to oxidative stress, 9) the consequences of age associated neurodegeneration, 10) to prevent neuronal cell death due to cell stress, 11) neurodegenerative events and intoxication, 12) to maintain and preserve normal neuronal cytoarchitecture during aging processes, 13) to support and/or improve synaptic function and synaptic density, 14) the consequences of the age-related decline of synaptic plasticity and of synaptic density, 15) to activate cerebral mechanisms related to attention and memory performance, 16) to prevent, counteract, and/or improve cognitive function decline, 17) to prevent, counteract, and/or improve

memory function decline, 18) to prevent, counteract, and/or improve attention deficits, 19) to prevent, counteract, and/or improve a decrease of vigilance associated with aging processes, 20) to support, maintain and or improve long term memory and procedural memory as well as learning performance, attention and vigilance, and 21) to preserve/support healthy mental function during the aging processes

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. That is, the species recited in claim 1, 9 and 11-15 are distinct from one another and would require separate and distinct searches. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-15 are generic with regards to the sequences and 9-15 are generic with regards to the methods.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37

CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. Applicant must elect one compound for claims 1-5, give the structural formula, including all functional groups, and the amino acid sequence of that compound with in the disclosure of each amino acid in its respective position in said sequence. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product, process of making, and process of using claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEANETTE LIEB whose telephone number is (571)270-3490. The examiner can normally be reached on 8:30am -5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEANETTE LIEB/
Examiner, Art Unit 1654

/CECILIA J TSANG/

Supervisory Patent Examiner, Art Unit 1654